Summary of H.R. 5629, the *Pathway for Biosimilars Act*

BIOSIMILAR BIOLOGICAL PRODUCTS APPROVAL PROCESS

Sets forth the requirements for FDA approval of a biological product as biosimilar to a reference product and provides a period of exclusivity for reference products and exclusivity for the initial interchangeable biosimilar.

Application – As part of an application to license a biological product as "biosimilar" to an approved reference biological product, biosimilar applicants must submit information demonstrating that their product is biosimilar to the approved reference biological product based

- analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;
- animal studies; and
- a clinical study or studies including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics.

The Secretary may waive the requirement for conducting these studies. However, in the case of waiver of immunogenicity assessment the Secretary must have issued guidance that the current state of scientific evidence allows for a determination of immunogenicity safety without the need for a study.

Interchangeability – The legislation provides a mechanism for the FDA to determine products are interchangeable. The Secretary must issue guidance advising that it is feasible in the current state of scientific knowledge to make a determination of interchangeability for that product class.

Exclusivity for First Interchangeable Biosimilar – To promote research and incentives to develop interchangeable products the legislation provides a period of exclusivity for the first product licensed as an interchangeable biosimilar.

Exclusivity for Reference Product – Provides for 12 years of data exclusivity for reference products.

- Promotes continued innovation by providing an additional 2 years of exclusivity for approval of a medically significant new indication that, if approved, would be a significant improvement over currently available therapies for the treatment or prevention of disease.
- Aligns incentives for pediatric studies in biologics with incentives for conducting pediatric studies in drugs by granting an additional 6 months of exclusivity for approval for use in pediatric populations.

Guidance Documents – The FDA must issue guidance documents for approval of biosimilars and must provide opportunity for public comment on any proposed guidance. The Secretary must issue final guidance for a product or product class before it can approve a biosimilar product.

- The Secretary must establish a process through which the public may provide input regarding priorities for issuing guidance.

- For currently approved products whose exclusivity period will expire in less than five year, a person may request the Secretary issue guidance for a particular product class and the Secretary must issue final guidance within two years of the request.

EXCHANGE OF INFORMATION REGARDING RELEVANT PATENTS

In order to identify relevant patents and resolve any patent disputes before the expiration of the products exclusivity period the legislation creates a structure for exchanging information between the innovator manufacturer, the biosimilar manufacturer and any third party patent holder.

- The FDA must publish notice identifying the reference product identified in a biosimilar application and notify the reference product sponsor within 30 days of acceptance, thereby initiating a timely process that enables biosimilar applicant and patent holders to identify relevant patents.
- Following the FDA notice, the reference product sponsor and any third-party patent holder must identify a list of relevant patents to the applicant, and an explanation of why these patents will be infringed.
- The applicant is then required to explain why the patents will not be infringed or are unenforceable, or state that it will not begin marketing the biosimilar until after the relevant patents expire. A product sponsor may then bring suit over any disputed patents and if successful, the FDA shall make approval of the biosimilar application effective after the expiration of the infringed patent.
- If the innovator does not bring suit the biosimilar applicant can bring suit asking for a declaratory judgment that it will not infringe any patents 3 years prior to the expiration of the reference product exclusivity.